Canadian Nuclear Safety Commission
Commission canadienne de sûreté nucléaire

REGULATORY GUIDE

Radiobioassay Protocols for Responding to Abnormal Intakes of Radionuclides

G-147

June 2003

Canada

REGULATORY DOCUMENTS

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RADIOBIOASSAY PROTOCOLS FOR RESPONDING TO ABNORMAL INTAKES OF RADIONUCLIDES

1.0 PURPOSE

This Regulatory Guide is intended to help licensees of the Canadian Nuclear Safety Commission (CNSC, Commission) ascertain and control radiation exposures and doses to workers in accordance with regulatory requirements, including the *Radiation Protection Regulations* and any relevant licence conditions.

2.0 SCOPE

This guide:

- describes two radiobioassay protocols that may be used by CNSC licensees to respond to situations where persons who perform duties in connection with activities authorized by the *Nuclear Safety and Control Act* and regulations may have experienced an abnormal intake of radioactive material; and
- provides advice on how to collect and handle radiobioassay samples.

3.0 BACKGROUND

3.1 Regulatory framework

The CNSC is the federal agency that regulates the use of nuclear energy and materials to protect health, safety, security and the environment, and to respect Canada's international commitments on the peaceful use of nuclear energy.

The *NSC Act* requires persons or organizations to be licensed by the CNSC for carrying out the activities referred to in section 26 of the Act, unless otherwise exempted. The associated regulations stipulate prerequisites for CNSC licensing, and the obligations of licensees and workers.

3.2 Relevant legislation

The *General Nuclear Safety and Control Regulations* and the *Radiation Protection Regulations* contain provisions that are relevant to this guide.

In particular:

- Paragraph 3(1)(e) of the *General Nuclear Safety and Control Regulations* stipulates that an application for a CNSC licence shall contain the proposed measures to ensure compliance with the *Radiation Protection Regulations*.
- Section 5 of the *Radiation Protection Regulations* stipulates:
  - "For the purpose of keeping a record of doses of radiation in accordance with section 27 of the Act, every licensee shall ascertain and record the amount of exposure to radon progeny of each person referred to in that section, as well as the effective dose and equivalent dose received by and committed to that person." [Subsection 5(1)]
  - "A licensee shall ascertain the amount of exposure to radon progeny and the effective dose and equivalent dose (a) by direct measurement as a result of monitoring; or (b) if the time

and resources required for direct measurement as a result of monitoring outweigh the usefulness of ascertaining the amount and doses using that method, by estimating them." [Subsection 5(2)]

- Section 6 of the Radiation Protection Regulations stipulates:
  - "In this section, 'action level' means a specific dose of radiation or other parameter that, if reached, may indicate a loss of control of part of a licensee's radiation protection program and triggers a requirement for specific action to be taken." [Subsection 6(1)]
  - "When a licensee becomes aware that an action level referred to in the licence for the purpose of this subsection has been reached, the licensee shall (a) conduct an investigation to establish the cause for reaching the action level; (b) identify and take action to restore the effectiveness of the radiation protection program implemented in accordance with section 4; and(c) notify the Commission within the period specified in the licence." [Subsection 6(2)]

- Paragraph 16(c) of the *Radiation Protection Regulations* stipulates:
  - "When a licensee becomes aware that a dose of radiation received by and committed to a person or an organ or tissue may have exceeded an applicable dose limit prescribed by section 13, 14 or 15, the licensee shall conduct an investigation to determine the magnitude of the dose and to establish the causes of the exposure."

The *Radiation Protection Regulations* do not stipulate how CNSC licensees are to ascertain exposures and doses to persons by "direct measurement as a result of monitoring." In the absence of such direction, section 4 of this guide describes two response protocols, involving the conduct of non-routine radiobioassays that can be used by CNSC licensees to ascertain the radiation dose to individuals when an abnormal intake of a radionuclide is known or suspected to have occurred.

3.3 Radiobioassay methods

The radiation protection programs that the *Radiation Protection Regulations* require of CNSC licensees will typically include provisions for radiobioassays. These radiobioassays may be "direct" or "indirect".

A "direct" (or "*in vivo*") radiobioassay is a measurement on the human body for the purpose of determining the amount of radioactive material in the body, utilizing instrumentation that detects the radiation emitted from the radioactive material.

An "indirect" (or "*in vitro*") radiobioassay consists of the collection and analysis of a sample of human hair, tissue, blood, urine or faeces for the purpose of determining the amount of radioactive material that might have been taken into the body.

3.4 "Routine" and "non-routine" radiobioassays

Direct and indirect radiobioassays to ascertain radiation doses may be further characterized as "routine" or "non-routine", as follows:

- a "routine" radiobioassay is any radiobioassay that involves collecting and analysing samples or taking measurements on the body at scheduled intervals, or at predetermined times, during normal operations.

- a "non-routine" radiobioassay is any radiobioassay that is implemented as part of an ad hoc response to a particular circumstance, such as a known or suspected intake of radioactive material due to an abnormal incident in the workplace. "Non-routine" radiobioassays are often termed "ad hoc" or "special" radiobioassays.

By definition, a dose monitoring program that includes routine radiobioassays is pro-active and precautionary in nature. Typically, such a program is intended to provide routine and timely detection, measurement and confirmation of any radioactive intakes that occur on an on-going basis during normal operations. An example of a routine radiobioassay is the submission of a biweekly (every 14 days) urine sample for analyses for the presence of tritiated water.

A monitoring program that consists only of non-routine radiobioassays is typically reactive and ad hoc in nature. Such a program is usually custom-designed for the purpose of obtaining key parameters that are necessary in order to conduct a specific dose assessment in response to a specific, identified need. To avoid prejudicing the results, a non-routine radiobioassay is typically performed with the subject individual removed from further contact with, or exposure to, radioactive substances.

Both routine and non-routine radiobioassays may involve one or more of the radiobioassay methods described in publications 54 and 78 of the International Commission on Radiological Protection (ICRP), or as otherwise determined to be appropriate to address case-specific needs.

3.5 Selecting and applying radiobioassay methods

In situations where response protocols involving non-routine radiobioassays are implemented, the associated program for conducting radiobioassays and analyses will typically depend upon case-specific factors, including:

- the time of intake of the radioactive contaminant(s);
- the mode of intake of the radioactive contaminant(s);
- the preliminary assessment of the radioactive intake and resulting dose, using the precipitating radiobioassay result and default parameters;
- whether the radiation is due to a single radionuclide or a mixture of radionuclides;
- the chemical and physical forms (e.g., particle size) of the radioactive contaminant(s);
- the types and energy of the radiation emitted by the contaminant(s);
- the rate of decay of the radioactive contaminant(s);
- the metabolic characteristics and behaviour of each suspected radioactive contaminant (e.g., retention time within the body, solubility within the body, rate of excretion from the body);
- when the radiobioassay results must be available;
- the number of radiobioassay results required; and
- the convenience, sensitivity, quality and suitability of the available radiobioassay equipment and facilities.

The radiobioassay methods that are most often used use to assess radiation doses from internal sources are *in vivo* counting, and the analysis of collected samples of excreta, such as urine and faeces. These methods are appropriate to a variety of situations. For example, radiobioassays of excreta may be the only reasonable option in a situation that involves radionuclides with no gamma-ray emissions or only low energy photon emissions. Conversely, where a person may have been internally exposed to a mixture of radionuclides that emits penetrating gamma photons, a combination of *in-vivo* counting, and the collection and analysis of excreta may be appropriate.

In certain situations where a standard radiobioassay method, or a combination of such methods, does not suffice to detect all radionuclides of concern, it may still be possible to use the method or combination of methods in conjunction with other knowledge or information to identify and estimate the impacts of all radionuclides of concern. For example, where standard methods indicate the presence of certain radionuclides, it may be reasonable to conclude that certain other radionuclides- i.e., those that are known to be normally associated with the radionuclides detected by the standard methods- are also present. The routine association, in irradiated uranium fuel, of ^{144}Ce (detectable by *in vivo* counting or gamma spectroscopy on faecal samples using germanium detectors) with certain transuranic radio nuclides is an example of such a situation. Accordingly, when a standard radiobioassay method detects a surrogate radionuclide (e.g., ^{144}Ce), that discovery, in light of the known or typical association of the surrogate with other radionuclides, may indicate that associated radionuclides that can only be detected by some supplementary *in vivo* counting techniques or special analyses (e.g., fission track analysis for ^{239}Pu in urine) are also present.

In addition, relevant metabolic data - such as organ or whole-body retention times, and urine and faecal excretion rates - can often be used (with appropriate adjustments) along with the results of radiobioassays to help ascertain the radiation exposures and doses from radioactive intakes.

4.0 RESPONSE PROTOCOLS

4.1 Application

The response protocols that are described in this section are intended to be used following suspected or actual intakes of significant quantities of radionuclides. Such intakes typically occur during abnormal incidents in the workplace, such as those involving:

- the breach or failure of a sealed source;
- the handling of unsealed radioactive sources;
- air-borne contamination as a consequence of fires or explosions; and
- the failure of personnel protection measures, such as respiratory equipment, during the maintenance or servicing of contaminated equipment or systems.

An abnormal incident that occurs at a CNSC-licensed facility or during a CNSC-regulated activity could trigger a requirement (under applicable legislation, a CNSC licence or the licensee's radiation protection program) for a non-routine radiobioassay.

In particular, when a licensee becomes aware that a dose to a person or an organ or a tissue may have exceeded an applicable dose limit prescribed by sections 13, 14 or 15 of the *Radiation Protection Regulations*, the licensee must conduct an investigation in order to determine the magnitude of the dose and to establish the causes of the exposure (Paragraph 16(c) of the *Radiation Protection Regulations*). The activities completed as part of the required investigation to determine the magnitude of the dose could include the conduct of a non-routine bioassay.

If the results of non-routine radiobioassays are to be credible, care should be paid to such details as the choice and application of assay methods, the timing and number of *in vivo* counts, or the timing of the collection of excreta samples relative to the time of intake of radiation. Accordingly, persons who are responsible for designing and implementing response protocols must exercise competent judgement on key matters. For example, they must decide whether to collect and retain

samples for confirmatory analyses, they must select appropriate times for truncation of sampling, and they must weigh and balance the associated advantages and disadvantages.

When selecting the preferred radiobioassay methods and identifying any complementary requirements for additional biological monitoring, the responsible persons should take into account the factors discussed in subsection 3.5 above.

The response protocols that are described in subsection 4.3 of this guide can be used by licensees to ascertain the committed effective dose resulting from an intake of radionuclides. However, users should exercise sound judgement. They should adjust and refine the recommended protocols to suit their specific needs and individual circumstances. These needs and circumstances will typically depend upon case-specific factors, including radiation hazards in the workplaces and the circumstances associated with the internal exposures.

4.2 Alignment with ICRP recommendations

The response protocols described in this guide are similar to those recommended in relevant annals of the ICRP. For example, "ICRP Publication 54" and "ICRP Publication 78" recommend, for a worker that intakes a significant quantity of radionuclides, that the worker's retention or excretion patterns and other relevant parameters be estimated, using individual-specific data. The ICRP prefers the use of individual-specific data over the application of standardized bio-kinetic models in such evaluations, because observed rates are typically more realistic than default values, and, thus, more likely to result in more realistic estimates of the associated radiation doses.

ICRP recommendations and the radiobioassay protocols described in this guide recognize that an individual's rate of retention or excretion cannot be adequately constructed on the basis of two or three randomly collected measurements or samples. Accordingly, these recommendations and protocols are designed to systematically yield individual-specific radiobioassay data that are sufficient to generate scientifically defensible dose assessments.

4.3 Description

4.3.1 Overview

The response protocols that are described below in subsections 4.3.3 and 4.3.2, and illustrated graphically in Figures 3 and 4 on pages 18 and 19 of this guide, address two specific situations. These situations are:

- When a routine radiobioassay program yields a result that is abnormal, and that indicates that a person may have been exposed to abnormal levels of radiation; and
- When the occurrence of an abnormal incident (e.g., an initiating event such as a fire, explosion, or a failure of a ventilation system) that has a recognized potential to give rise to significant intakes of radionuclides by an affected person is known or suspected.

Figures 1 and 2 on pages 16 and 17 of this guide illustrate excretion-sampling patterns that could be appropriate in specific situations. These figures take into account the

anatomical and physiological characteristics defined by the ICRP for reference individuals in ICRP Publication 23.

Figure 1 shows a typical schedule for sampling faecal excretions that may contain a "Type S compound". A "Type S compound" is a compound that is relatively insoluble in the human respiratory tract, and thus only absorbed into the blood of the tract slowly.

Figure 2 shows a typical schedule for sampling urine excretions that may contain a "Type F compound". A "Type F compound" is a compound that is relatively soluble in the human respiratory tract, and thus readily absorbed into the blood of the tract.

4.3.2 A response protocol triggered by a routine radiobioassay

Removing workers, confirming radiobioassay results, estimating doses and retaining samples

As the first phase of this recommended response protocol:

- Remove the exposed individual from any possibility of further intake.
- Confirm the precipitating radiobioassay result as soon as practical, using the laboratory that performed the analysis.
- Perform preliminary assessments of intake and dose using the results of the initial radiobioassays, taking factors such as those presented in subsection 3.5 of this guide into account.
- If the precipitating result is unusually high (i.e., much greater than a relevant "action level", as defined in subsection 6.1 of the CNSC *Radiation Protection Regulations*) consider confirming it with a laboratory that is independent of the laboratory that obtained the precipitating result.
- Where possible, when routine radiobioassays of a sample yield elevated results, retain the precipitating sample until all investigations associated with the incident are complete.

Typically, samples can be most conveniently retained for use in repeat or additional analyses when only a small portion of the total collection is required for each analysis. For example, each determination of tritium in tritiated water in urine typically requires only 5 ml of urine, whereas the typical volume of a urine sample may range from 0.1 L to 1 L. Accordingly, a relatively small sample of urine, which occupies commensurate storage space, is sufficient for several "tritium" analyses.

Where practical, the unused portions of a urine or faecal sample should be retained for further analyses. For example, when non-destructive gamma spectroscopy of a faeces sample indicates significantly elevated levels of fission and activation products, it may be both practical and prudent to reduce the sample to ash, and to save a portion of the ash for further analyses. In a few situations, it might be worthwhile to retain the unused

portion of a sample until such time as improvements in analytical techniques or equipment give rise to more sensitive, accurate or reliable results.

Section 5 of this guide provides guidance on how to handle and store radiobioassay samples.

Determining and implementing the program of non-routine sampling and radiobioassays

As part of this protocol, non-routine sampling and radiobioassays are required in response to a routine bioassay that indicates that a worker has received a radiation dose or radioactive intake that exceeds a regulatory limit, or that equals or exceeds a relevant "action level", as defined in subsection 6(1) of the *Radiation Protection Regulations.*

To be effective, a follow-up program of non-routine bioassays must take relevant factors into account. These factors include the considerations discussed in subsection 3.5 of this guide, the sampling and counting recommendations in Table 1 on page 15 of this guide, the radiation protection program, and the characteristics of the radionuclides involved.

Table 1 on page 15 of this guide recommends biological sampling and *in vivo* counting campaigns for three contiguous time periods ("1-10 days", "10-100 days", and "More than100 days"), following a routine bioassay that indicates that a radioactive intake equals or exceeds an action level. The recommendations of Table 1 cover the time period during which the exposed person is removed from further work involving radiation or radioactive substances in the workplace.

Table 1 addresses many, but not all, situations that are likely to be encountered by CNSC licensees. For example, where short-lived radionuclides (i.e., half-life less than 3 days) are of concern, the time that is available for the purpose of conducting effective sampling will be commensurately short, and consequently the sampling regime recommended in Table 1 may not be entirely appropriate. Similarly, the recommendations of Table 1 may not be entirely appropriate in situations where long-lived radionuclides are incorporated into compounds that have short half-lives (less than 3 days). For such situations, sample daily during the 10 days that immediately follow intake in order to accurately define the shapes of the individual's retention or excretion curves.

Where the results of a routine radiobioassay indicate that a worker's intake of radioactive material may be greater than a relevant action level, arrange for the non-routine sampling and radiobioassays recommended in Table 1, and for any supplementary biological samplings (e.g., of blood, saliva or breath) and radiobioassays that are required by the applicable radiation protection program, or necessary in order to generate or improve estimates of radioactive intake or radiation doses. For example, when an estimated dose exceeds 100 mSv, collect blood samples for chromosomal analyses.

4.3.3 A response protocol triggered by an abnormal incident

Application of this response protocol

This protocol is intended to be implemented in response to abnormal incidents in the workplace, such as accidents involving fire, explosions, or failure of ventilation systems. Abnormal incidents typically increase the levels of airborne radioactivity, and can result in increased intakes of radioactive materials by affected workers.

Assessing whether and when an intake may have occurred

Because incidents such as fires, explosions or ventilation failures may be self-evident or typically trigger protective alarms or monitors, their times of occurrence are usually well-known. When this is so, the time of any associated intake of radioactive contaminants by workers can typically be established with similar accuracy.

Following an abnormal incident at a nuclear facility, an increased intake by workers may be suspected from indirect evidence. For example, the detection of facial or nasal contamination by portal monitors or hand-held detectors, or the presence of surface cuts or sores that are radioactively contaminated, may indicate that the individuals has been subjected to airborne contamination. Such evidence can be sufficient reason to immediately initiate a non-routine radiobioassay, instead of awaiting the results of routine radiobioassay monitoring.

Where an intake of radioactive contaminants is suspected but not confirmed, the timely collection of non-radiobioassay and radiobioassay samples may help establish whether or not such an incident has occurred.

Non-radiobioassay samples include swabs of nasal fluid, and surface wipes of protective clothing or workplace surfaces. Either the presence of radionuclides in such media, or the lack thereof, can serve as a reasonable indicator of whether an inhalation incident has occurred.

Collecting samples, confirming results, and estimating doses

- Arrange for the timely collection of radiobioassay samples from the exposed individuals and the timely completion of *in vivo* counting, since the initial results of the radiobioassay or *in vivo* monitoring will influence decisions about further sampling.
- If widespread contamination is present, take particular care to obtain uncontaminated radiobioassay samples (see section 5 below).
- While awaiting the results of the initial radiobioassay sampling and the initial *in vivo* monitoring, continue to sample at the frequencies recommended in Table 1 on page 15.

- Review the results of the initial *in vitro* radiobioassay or *in vivo* counting, and compare them with the results of the available non-radiobioassay samples, such as nasal swabs or surface contamination wipe samples.

- If the radionuclides detected in the nasal swab and workplace wipe samples are the same as those reported in the radiobioassay results, consider this agreement to be a confirmation that a corresponding radioactive intake has occurred.

- Perform preliminary assessments of intake and dose using the results of the initial radiobioassays results, taking factors such as those presented in subsection 3.5 of this guide into account.

Possible responses to the preliminary assessments of intake and dose

- If the estimated intake or dose is less than a relevant "action level", as defined in subsection 6.(1) of the CNSC *Radiation Protection Regulations*, adjust the protocols recommended in Table 1 accordingly. Since the intake is relatively low, consider ending sampling much sooner than recommended in the table.

- If the estimated intake or dose is equal to or greater than a relevant "action level", as defined in subsection 6.(1) of the CNSC *Radiation Protection Regulations*, follow the protocols recommended in Table 1. If appropriate, arrange for additional specialized analyses and biological monitoring, as discussed in subsections 3.5 and 4.1, respectively. For example, if the estimated dose may exceed 100 mSv, collect blood samples for chromosomal analyses.

5.0 COLLECTING AND HANDLING RADIOBIOASSAY SAMPLES

5.1 General rules

- Ensure that all persons who handle radiobioassay samples are properly instructed in the safe handling of biological and radioactive specimens.

- Use the services of a qualified medical agency or practitioner to collect blood samples.

- When collecting samples in restricted zones, work in areas where the probabilities of contamination of the samples are lowest.

- Collect all samples in sterile disposable containers.

- When a faecal sample is required from a subject, instruct the subject to exercise caution to avoid contaminating the required sample with urine

- After collecting a sample in a potentially-contaminated workplace, shower or wash your hands carefully before removing the samples to an unrestricted area.

- Where possible, retain all samples collected until all investigations associated with the incident are complete.

5.2 Labelling samples

- After collecting a radiobioassay sample from a person, label the sample container with the name or identification number of the person, and the date and time of sample collection.

5.3 Treating and storing urine samples

- If the urine sample is to be retained for more than 24 hours before it is analysed, place the sample in cold storage (such as in a refrigerator or cooler) immediately following its collection.

- If a urine sample is to be retained for a significant or indeterminate period of time before it is analysed, treat the sample to prevent or minimize bacterial growth or radionuclide losses to the walls of the sample container, immediately following the collection of the sample. Use measures that are appropriate to the situation, taking into account the characteristics and chemical forms of the radionuclides present in the sample. Typical approaches include adding acid to certain types of samples to prevent precipitation, or adding a preservative such as thymol to minimize bacterial growth.

- Where appropriate, urine samples may be preserved by freezing. Freezing may be particularly appropriate and convenient for urine samples containing organically-bound tritium, particularly those which may require a repeat or confirmatory analysis to determine the organically-bound tritium present in the sample. Where possible, retain part of the collected samples for repeat or multiple analyses.

5.4 Collecting and storing faecal samples

- When collecting faecal samples, use specialty kits (e.g., a "commode specimen collection system") that are designed for the purpose, and readily available from commercial medical equipment suppliers.

- Upon receiving faecal samples that are not to be analyzed immediately, freeze them.

5.5 Packaging and transporting radiobioassay samples

- To prevent discharge, emission or loss of radiobioassay samples during transport, package them securely in accordance with paragraph 2.3.3(b) of the *Transportation of Dangerous Goods Regulations*. Pay particular attention to the packaging of liquids and fluid samples.

- If liquid radiobioassay samples are to be more than two hours in transport, package them in a cooler containing dry ice.

- Maintain faecal samples in a frozen state during transport.

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